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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/480,544	01/10/2000	JOHN H. KENTEN	0039096-0030	4434

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EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	**PAPER NUMBER**
1634	11

DATE MAILED: 02/28/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/480,544	Kenten et al.
Examiner	**Art Unit**
Arun Chakrabarti	1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- *Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.*
- *If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.*
- *If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.*
- *Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).*
- *Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).*

Status

1) ☒ *Responsive to communication(s) filed on Jan 16, 2002 .*

2a) ☐ *This action is* **FINAL.** 2b) ☒ *This action is non-final.*

3) ☐ *Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.*

Disposition of Claims

4) ☒ *Claim(s) 32-43 is/are pending in the application.*

4a) *Of the above, claim(s) _____ is/are withdrawn from consideration.*

5) ☐ *Claim(s) _____ is/are allowed.*

6) ☒ *Claim(s) 32-43 is/are rejected.*

7) ☐ *Claim(s) _____ is/are objected to.*

8) ☐ *Claims _____ are subject to restriction and/or election requirement.*

Application Papers

9) ☐ *The specification is objected to by the Examiner.*

10) ☐ *The drawing(s) filed on _____ is/are objected to by the Examiner.*

11) ☐ *The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.*

12) ☐ *The oath or declaration is objected to by the Examiner.*

Priority under 35 U.S.C. § 119

13) ☐ *Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).*

a) ☐ *All* b) ☐ *Some** c) ☐ *None of:*

1. ☐ *Certified copies of the priority documents have been received.*
2. ☐ *Certified copies of the priority documents have been received in Application No. _____ .*
3. ☐ *Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).*

**See the attached detailed Office action for a list of the certified copies not received.*

14) ☐ *Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).*

Attachment(s)

15) ☒ *Notice of References Cited (PTO-892)*

16) ☐ *Notice of Draftsperson's Patent Drawing Review (PTO-948)*

17) ☐ *Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____*

18) ☐ *Interview Summary (PTO-413) Paper No(s). _____*

19) ☐ *Notice of Informal Patent Application (PTO-152)*

20) ☐ *Other:*

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CAR 1.114, including the fee set forth in 37 CAR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CAR 1.114, and the fee set forth in 37 CAR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CAR 1.114. Applicant's submission filed on January 16, 2002 has been entered.

Specification

2. Claims 21-31 have been cancelled without prejudice towards further prosecution. New claims 32-43 have been added.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 32-43 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Malek et al. (U.S. Patent 5,130,238) (July 14, 1992) in view of Earle et al (U.S. Patent 5,925,518) (July 20, 1999).

Malek et al teaches a process for the detection of a specific nucleic acid sequence (Abstract and Figure 1A), comprising the steps of:

(a) the sample (claim 1, column 22, lines 57-58) comprising

(I) a first oligonucleotide primer (claim 1, column 22, line 59) ,

(ii) a second oligonucleotide primer comprising an antisense sequence of a promoter (claim 1, column 22, lines 60-61),

(iii) a DNA-directed RNA polymerase that recognizes the promoter (claim 1, column 22, lines 62-63),

(iv) an RNA-directed DNA polymerase (claim 1, column 22, lines 64),

(v) a DNA-directed DNA polymerase (claim 1, column 22, lines 65),

(vi) a ribonuclease that hydrolyzes RNA of an RNA-DNA hybrid without hydrolyzing single or double-stranded DNA (claim 1, column 22, lines 66-68),

(b) incubating the reaction mixture for a sufficient time to amplify the specific nucleic acid sequence to form an amplified nucleic acid sequence mixture comprising an amplified nucleic acid sequence (claim 1, column 23, lines 4-8);

Malek et al teaches a process wherein

(I) the first oligonucleotide primer hybridizes to the RNA first template (claim 1, column 23, lines 9-10),

(ii) the RNA-directed DNA polymerase uses the RNA first template to synthesize a DNA second template by extension of the first oligonucleotide primer and thereby forms an RNA-DNA hybrid intermediate (claim 1, column 23, lines 11-15),

(iii) the ribonuclease hydrolyses RNA which comprises the RNA-DNA hybrid intermediate (claim 1, column 23, lines 16-17),

(iv) the second oligonucleotide primer hybridizes to the DNA second template (claim 1, column 23, lines 18-19),

(v) the DNA-directed DNA polymerase uses the second oligonucleotide primer as template to synthesize the promoter by extension of the DNA second template (claim 1, column 23, lines 20-23),

(vi) the DNA-directed RNA polymerase recognizes the promoter and transcribes the second template, thereby providing copies of the RNA first template (claim 1, column 23, lines 24-27); and thereafter

c) maintaining the conditions for a time sufficient to achieve a desired amplification of the specific nucleic acid sequence (claim 1, column 23, lines 28-31).

Malek et al teaches a process wherein step (b) comprises adding to the reaction medium single-stranded DNA which comprises an antisense sequence of the promoter (Claim 10, lines 59-65).

Malek et al teaches a process wherein step (b) comprises adding to the reaction medium and RNA-DNA hybrid comprising the single-stranded DNA, such that the ribonuclease hydrolyzes RNA which comprises the RNA-DNA hybrid (Claim 5, column 24, lines 25-29).

Malek et al teaches a process wherein step (b) comprises adding to the reaction medium single-stranded DNA which comprises the DNA second template, such that

(I) the second oligonucleotide primer hybridizes to the single-stranded DNA (claim 6, column 24, lines 34-35),

(ii) the DNA-directed DNA polymerase uses the second oligonucleotide primer as template to synthesize the promoter by extension of the DNA second template (claim 6, column 24, lines 36-39), and

(iii) the DNA-directed RNA polymerase recognizes the promoter and transcribes the DNA second template, thereby providing copies of the RNA first template (claim 6, column 24, lines 40-43).

Malek et al teaches a process wherein step (b) comprises adding to the reaction medium a DNA comprising the promoter, such that the DNA-directed RNA polymerase transcribes the DNA, thereby synthesizing the single-stranded RNA (claim 8, column 24, lines 49-53).

Malek et al teaches a process wherein step (b) comprises adding to the reaction medium a DNA comprising the promoter, such that the DNA-directed RNA polymerase transcribes the DNA, thereby synthesizing the single-stranded RNA (claim 9, column 24, lines 54-58).

Malek et al teaches a process wherein the RNA-directed DNA polymerase is a retrovirus reverse transcriptase (claim 30, column 26, lines 4-6).

Malek et al teaches a process wherein the DNA-directed DNA polymerase lacks exonuclease activity (claim 33, column 26, lines 13-15).

Malek et al teaches a process wherein all DNA polymerase in the reaction medium lack exonuclease and DNA endonuclease activity (claim 34, column 26, lines 16-18).

Malek et al teaches a process wherein the DNA-directed DNA polymerase is DNA polymerase alpha or DNA polymerase beta.

Malek et al does not teach the addition of;

(I) at least one probe sequence complementary to the RNA first template labeled with an electrochemiluminescent species comprising ruthenium-tris-bipyridine,

(ii) at least one second capture probe sequence complementary to the RNA first template labeled with a binding species selected from biotin,

(iii) a bead coated with a complementary binding species to the second probe sequence; and thereafter

(d) providing conditions of temperature and buffer to allow the hybridization of the probes to the first RNA template and the binding of the binding species on the second capture probe with the complementary binding species on the bead to form a bead bound complex; and then

(e) detecting the bead bound complex using the electrochemiluminescent species.

Earle et al teaches the addition of;

(I) at least one probe sequence complementary to the RNA first template labeled with an electrochemiluminescent species comprising ruthenium-tris-bipyridine (Example 1, column 10, lines 5-12 and column 7, line 31 to column 8, line 17),

(ii) at least one second capture probe sequence complementary to the RNA first template labeled with a binding species selected from biotin (Example 1, column 10, lines 7-12 and column 7, line 31 to column 8, line 17)

(iii) a streptavidin-coated magnetic bead with a complementary binding species to the second probe sequence (Example 1, column 10, lines 7-10); and thereafter

(d) providing conditions of temperature and buffer to allow the hybridization of the probes to the first RNA template and the binding of the binding species on the second capture probe with the complementary binding species on the bead to form a bead bound complex (Example 1, column 10, lines 12-14); and then

(e) detecting the bead bound complex using the electrochemiluminescent species.(Example 1, column 10, lines 12-19 and Figure 2, Table 2).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the detection of hybridization by bead bound complex with electrochemiluminescent species model of Earle et al. in the enhanced nucleic acid amplification method of Malek et al. since Earle et al. states , "Any of these methods could significantly reduce the time required for diagnosis of infection with M. Tuberculosis, perhaps to as little as one day(Column 1, lines 54-56)". An ordinary practitioner would have been motivated to combine the detection of hybridization by bead bound complex with electrochemiluminescent species model of Earle et al. in the enhanced nucleic acid amplification method of Malek et al in order to achieve the express advantages noted by Earle et al. of a system which could significantly reduce the time required for diagnosis of infection perhaps to as little as one day.

Response to Amendment

5. In response to amendment, double-patenting rejection has been withdrawn and new 103 (a) rejection has been included.

Response to Arguments

6. Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Arun kr. Chakrabarti

Arun Chakrabarti,

Patent Examiner,

February 5, 2002